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(54) Title: SUSTAINED RELEASE ORAL DOSAGE FORMS OF GABAPENTIN

(57) Abstract: The present invention relates to sustained release oral dosage forms of gabapentin and at least one rate controlling polymer, and a process for the preparation of the sustained release oral dosage forms, and a process for the preparation thereof. The sustained release tablet includes gabapentin or a pharmaceutically acceptable salt or hydrates thereof and at least one rate-controlling polymer such that the tablet provides therapeutically effective plasma levels of gabapentin for a period of up to about 12 hours.

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K9/22 A61K31/195

C. DOCUMENTS CONSIDERED TO BE RELEVANT

A61P25/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

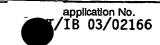
EPO-Internal, WPI Data, PAJ, MEDLINE, EMBASE, BIOSIS, CHEM ABS Data

Category °	Citation of document, with indication, where appropriate, of the	relevant passages	Relevant to claim No.	
X	WO 00 76478 A (CIP NINETY TWO 93; AJANI MAURO (PA); VILLA ROBERTO FOSSA) 21 December 2000 (2000-13) examples 1,5 claims 1,7,13	O (PA);	1–53	
X	WO 00 59477 A (JANS EUGENE MARII; JANSSEN PHARMACEUTICA NV (BE); VANDECRUYS) 12 October 2000 (200 page 5, line 5 - line 36 page 7, line 21 page 11, line 19 -page 12, line claims 1,19	00-10-12)	1-53	
X Further documents are listed in the continuation of box C. X Patent family members are listed in annex.				
 "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is clied to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but 		To later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention. It document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.		
Date of the a	actual completion of the international search	Date of mailing of the international sea	rch report	
8 October 2003		16/10/2003		
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016		Authorized officer Hedegaard, A		

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	ation) DOCUMENTS CONSIDERED SE RELEVANT	Delay-the data is
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 51033 A (BERWAER MONIQUE ;DELEERS MICHEL (BE); FANARA DOMENICO (BE); UCB SA) 19 July 2001 (2001-07-19) tables 2,4,6 claims 1,2,8	1-53
P,X	WO 03 002151 A (MASSIRONI MARIA GABRIELLA ;FARMATRON LTD (GB)) 9 January 2003 (2003-01-09) example 4 claims 1,8,11,12	1-53
P,X	WO 03 035040 A (DEPOMED INC) 1 May 2003 (2003-05-01) examples 1-4 claims 1,12,19	1–53
A	EP 0 284 849 A (LEK TOVARNA FARMACEVTSKIH) 5 October 1988 (1988-10-05) the whole document	1–53
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Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)		
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:			
1. χ	Claims Nos.: — because they relate to subject matter not required to be searched by this Authority, namely:		
2.	Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy. Although claims 49-53 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition. Claims Nos.:		
_	because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:		
з. 🔲	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).		
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)		
This Inte	ernational Searching Authority found multiple inventions in this international application, as follows:		
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.		
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.		
3.	As only some of the required additional search fees were timely paid by the applicant, this international Search Report covers only those claims for which fees were paid, specifically claims Nos.:		
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:		
Remark	The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.		

PCT/I /02166 Patent family Patent document ublication **Publication** cited in search report date member(s) date WO 0076478 Α 21-12-2000 IT MI991317 A1 14-12-2000 IT MI20000422 A1 03-09-2001 ΑU 02-01-2001 5680100 A CA 2377301 A1 21-12-2000 CN 26-06-2002 1355693 T WO 21-12-2000 0076478 A1 EP 06-03-2002 1183014 A1 JP 2003501457 T 14-01-2003 NO 20016108 A 24-01-2002 21-05-2002 TR 200200562 T2 23-10-2000 WO 0059477 12-10-2000 3963800 A Α ΑU 30-04-2002 BG 105857 A BR 0009437 A 15-01-2002 CA 2371940 A1 12-10-2000 CN 1345233 T 17-04-2002 CZ 20013375 A3 15-05-2002 EE 200100505 A 16-12-2002 WO 0059477 A1 12-10-2000 EP 1169024 A1 09-01-2002 HR 20010700 A1 30-04-2003 HU 0200611 A2 29-07-2002 JP 2002541090 T 03-12-2002 NO 20014724 A 28-09-2001 NZ 514890 A 30-05-2003 SK 13542001 A3 06-08-2002 WO 0151033 Α 19-07-2001 EP 1118321 A1 25-07-2001 24-07-2001 ΑU 2169501 A WO 0151033 A1 19-07-2001 WO 03002151 A 09-01-2003 IT MI20011337 A1 27-12-2002 WO 03002151 A1 09-01-2003 WO 03035040 Α 01-05-2003 WO 03035040 A1 01-05-2003 US 2003100611 A1 29-05-2003 EP 0284849 05-10-1988 YU Α 40687 A1 28-02-1991 DE 3882765 D1 09-09-1993 DE 3882765 T2 10-03-1994 EP 0284849 A1 05-10-1988 JP 2025714 C 26-02-1996 JP 7057726 B 21-06-1995 JP 63290818 A 28-11-1988 8710406 A ,B SI 31-08-1996

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